Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of informational support on anxiety and satisfaction of family caregivers of patients with hemiplegic stroke

Protocol summary

Summary

Objective: This study will be done to evaluate the effect of informational support on the satisfaction and anxiety of family caregivers of patients with hemiplegic stroke. Design: This study is a quasi-experimental clinical trial with two groups (intervention and control) and pre-test - post-test design. Setting and conduct: This study will be done by participating 84 family caregivers of stroke hemiplegic patients admitted to hospital neurology Farshchian (Sina) in Hamadan. Each group consists of 42 patient's people. Participants, including major eligibility criteria: The family member is responsible for the patient care; minimum age of 18 years; ability to read and write; lack of neurological disease, mental illness and anxiety; lack of drugs and psychotropic substance abuse; lack of communication problems; Be able to speak and understand the language of Farsi; unemployment in health centers. Exclusion criteria: Don't have willingness family caregivers to continue to study at any moment; death of the patient; family member cannot participate in all educational sessions; creating unwanted problems for the patient, such as re-bleeding and severe hemodynamic disorders that affect on the family. Intervention: In experimental group, family caregivers will receive some informational support that is consist of introductory neurology ward tour, training sessions and educational booklet and pamphlet about matters related to stroke. No intervention will be done in control group. In both groups will be measure level of anxiety by Spielberger questionnaire and family caregiver's satisfaction by satisfaction of information questionnaire before and after the intervention. Main outcome measure: The main outcome is the anxiety and satisfaction of information on family caregivers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022032129N2**
Registration date: **2017-04-21, 1396/02/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-04-21, 1396/02/01

Registrant information

Name

Azim Azizi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology of Hamadan University of Medical Sciences

Expected recruitment start date

2017-04-09, 1396/01/20

Expected recruitment end date

2017-09-11, 1396/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of informational support on anxiety and satisfaction of family caregivers of patients with

hemiplegic stroke

Public title
The effect of informational support on anxiety and satisfaction of family caregivers
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: The family member is responsible for the patient care; minimum age of 18 years; ability to read and write; lack of neurological disease, mental illness and anxiety; lack of drugs and psychotropic substance abuse; lack of communication problems; Be able to speak and understand the language of Farsi; unemployment in health centers. Exclusion criteria: Don't have willingness family caregivers to continue to study at any moment; death of the patient; family member cannot participate in all educational sessions; creating unwanted problems for the patient, such as re-bleeding and severe hemodynamic disorders that affect on the family.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamedan University of Medical Sciences
Street address
Hamadan University of Medical Sciences, Shahid Fahmide boulevard, Hamadan
City
Hamadan
Postal code
009881338380717
Approval date
2017-01-20, 1395/11/01
Ethics committee reference number
IR.UMSHA.REC.1395.529

Health conditions studied

1

Description of health condition studied
stroke
ICD-10 code
G46.4
ICD-10 code description
Cerebellar stroke syndrome

Primary outcomes

1

Description
The anxiety in caregivers of patients with stroke
Timepoint
8 days before and after the intervention.
Method of measurement
Anxiety Inventory (STAI)

2

Description
satisfaction of information
Timepoint
8 days before and after the intervention
Method of measurement
satisfaction of information questionnaire

Secondary outcomes

1

Description
The satisfaction of caregivers of patients with stroke
Timepoint
8 days before and after the intervention.
Method of measurement
Family caregivers satisfaction

Intervention groups

1

Description
The intervention study was conducted in two phases the first phase information support family caregivers for individual training, oral and face-to-face patient care to the patients and their relatives were tailored to the needs.The second stage consists of two one-hour group training session focused on the overall needs of patients with stroke and their carers group discussion about the problems and concerns as every other day will be held. The manual includes general information about stroke,

its cause, explanation about the different aspects of treatment, including surgery, adverse events, patient's diet, the symptoms and how to prevent it, how to deal with disabilities

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Educational and Medical Center

Full name of responsible person

Zhaleh Mollaei

Street address

Mirzadeheshghi St. Farshchian Educational and Medical Center

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences, Vice chancellor for Research

Full name of responsible person

Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmide boulevard, Hamadan

City

Hamadan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamadan University of Medical Sciences, Vice chancellor for Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Azim Azizi

Position

PhD in Nursing

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty